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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,475	05/31/2001	Monika Lusky	017753-146	7808
21839	7590	06/02/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MARVICH, MARIA	
POST OFFICE BOX 1404				
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,475

Applicant(s)

LUSKY ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-37 is/are pending in the application.
- 4a) Of the above claim(s) 31,34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-30,32-33,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/493,486.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

This office action is in response to an amendment filed 3/24/04. Claims 2 and 5 are cancelled. Claims 1, 3, 4, 6-19, 22, 23, 26, 28, 36, and 37 have been amended. Claims 1, 3, 4 and 6-37 are pending. Claims 31 and 34-35 are withdrawn.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-30, 32-33 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the term, "genomes of both (i) and (ii) comprising" ITRs, encapsidation region and genes of early and late are unclear. It is unclear whether each genome individually comprises of each of the listed components or collectively the genomes comprise these components. **This rejection is maintained for reasons of record in the office action filed 12/24/03 and restated here.**

Art Unit: 1636

Claims 1(b), 1(e) and 36 recite the limitation "the cell obtained in step (a)" in claim 1. There is insufficient antecedent basis for this limitation in the claim. In fact, the cell may be considered to be obtained prior to the introduction step whereas the limitation appears to intend the use of a cell generated following step (a). **This is a new rejection.**

Claim 6 is vague and indefinite in that the metes and bounds of "said first helper (i) or said second helper (ii) **and** said first helper (i) and said second helper (ii)" are unclear. It is unclear how the defective mutants can be the first or second AND first and second. **This is a new rejection is necessitated by applicants' amendment.**

Claim 12 recites the limitation "said second helper vector" in claim 11. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection necessitated by applicants' amendment.**

Claim 13 recites the limitation "the E1 function" in claim 1. There is insufficient antecedent basis for this limitation in the claim. **This is a new rejection.**

Claim 13 is vague and indefinite in that the metes and bounds of "functional for the E1 function" are unclear. Firstly, E1 has more than one function thus it is unclear if all or one are intended to be "functional" as the claim recites **the function**. If it is one function as written, it is unclear which of the functions is to be "functional". Secondly, functional E1 function is redundant. **This is a new rejection.**

Claim 15 and 17 are vague and indefinite in that the metes and bounds of "make the origin of replication recognized" are unclear. It is unclear how modification of a vector can "make" the origin "recognized". Use of the word "enable" instead of "make" would be appropriate. And a verb is required prior to "recognized". **This is a new rejection.**

Art Unit: 1636

Claim 16 is vague and indefinite in that the metes and bounds of “replacement” “by” are unclear. Use of the verb “by” is improper and should be “with”. **This is a new rejection.**

Claim 25 recites the limitation “at least one defective function” in claim 24. There is insufficient antecedent basis for this limitation in the claim. The recombinant minimal vector is not said to have any defective functions. **This is a new rejection.**

Response to Arguments

Applicants’ traverse the rejection of claim 1 on page 13 of the amendment filed 3/24/04. Applicants argue that each genome (i) and (ii) individually comprises each of the listed components as the plural form of “genomes” indicates such.

The arguments filed 3/24/04 have been considered but are not persuasive. The use of the plural form “genomes” does not distinguish as to whether the “genomes” collectively or each comprise the 5’ and 3’ ITRs, an encapsidation region and one or more genes of the early and late regions. By reciting “genomes of both (i) and (ii)”, the genomes could both individually or both collectively comprise the listed components.

Conclusion

Claims 1, 3-4, 6-30, 32-33 and 36-37 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

May 18, 2004


GERRY LEFFERS
PRIMARY EXAMINER